

REMARKS

Claims 1-9 are pending.

112, 1st Paragraph, Rejection

Claim 7 stands rejected under 35 U.S.C. 112, 1st paragraph, as allegedly failing to comply with the enablement requirement with respect to the claim language “the poly-3-hydroxyalkanoic acid-containing microbial cells are cells of a strain of microorganism transformed by a poly-3-hydroxyalkanoic acid synthase group gene derived from *Aeromonas caviae*.” Applicants first point out that the rejected claim language is in claim 9, rather than claim 7. Accordingly, Applicants respond to the rejection with respect to claim 9. Applicants traverse the rejection.

The specification clearly discloses the strain of microorganism transformed by a poly-3-hydroxyalkanoic acid synthase group gene derived from *Aeromonas caviae*. For example, the specification, page 8, ll. 5-14, describes an example of the claimed strain, *Alcaligenes eutrophus* AC32 (FERM BP-6038). Therefore, a person skilled in the art would be enabled by the specification how to make and/or use the claimed strain. Moreover, the presence of such a strain as described in the specification provides enablement for the person skilled in the art.

Therefore, Applicants submit that claim 9 complies with the enablement requirement. Withdrawal of the rejection is therefore requested.

102(b)/103(a) Rejections

Claims 1-7 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as allegedly obvious over Choi, et al., “Efficient and Economical Recovery of Poly(3-Hydroxybutyrate) from Recombinant *Escherichia coli* by Simple Digestion with Chemicals,” Biotechnology and Bioengineering, Vol. 62, No. 5, March 5, 1999, pp. 546-553 (“Choi”) or Harrison, et al., “Combined chemical and mechanical processes for the disruption of bacteria,” Bioseparation, Vol. 2, No. 2, 1991, pp. 95-105 (“Harrison”). Applicants traverse the rejections.

Claim 1 is directed to a method of producing a poly-3-hydroxyalkanoic acid (PHA), which comprises carrying out a physical disruption treatment of a suspension of PHA-containing microbial cells with adding an alkali thereto either continuously or intermittently

and, thereafter, separating the PHA.

Choi

Choi discloses recovery of poly-3-hydroxybutyrate (P(3HB)) from recombinant *Escherichia coli* by digestion of non-P(3HB) cellular material (NPCM) with chemicals. See, e.g., Choi, Abstract. Choi discloses various chemical solutions that were added to cells resuspended in water and then mixed together. See, e.g., Choi, p. 548, left column, “P(3HB) Recovery by Simple Digestion of NPCM.” However, Choi discloses neither that physical disruption treatment is carried out nor that physical disruption treatment is carried out with adding an alkali, as in Applicants’ claim 1.

Moreover, there is neither teaching nor suggestion in Choi to modify its method to provide Applicants’ claimed method.

Furthermore, Applicants have discovered that, by the physical disruption treatment being carried out with adding an alkali, the cells may be disrupted and the released constituents micronized, e.g., nucleic acid may be fractionated and degraded, which advantageously prevents viscosity elevation and promotes alkali solubilization of insoluble substances, thus contributing to enhanced PHA yields. See, e.g., specification, page 10, ll. 23-27; page 11, ll. 4-15. This may advantageously be in addition to nucleic acid and insoluble substances such as cell wall being released along with PHA from the microbial cells by the alkali treatment. The unexpected results of Applicants’ claimed physical disruption treatment being carried out with alkali treatment can not be predicted from Choi’s disclosure.

Therefore, for at least the above reasons, claim 1 and its dependent claims 2-7 are believed to be neither anticipated by nor obvious over Choi. Withdrawal of the rejections is therefore requested.

Harrison

Harrison discloses chemical pretreatment followed by mechanical disruption of bacteria. See, e.g., Harrison, Abstract. Harrison discloses that the use of chemical pretreatment to decrease cell wall strength *prior to* mechanical breakage by homogenization has been considered. See *id*; Table 1. Harrison further discloses homogenization being carried out at neutral pH after alkaline pretreatment and neutralization treatment. See, e.g.,

Harrison, page 98, left column, ll. 9-17. However, Harrison does not disclose physical disruption treatment being carried out *with* adding an alkali, as in Applicants' claim 1.

Moreover, there is neither teaching nor suggestion in Harrison to modify its method to provide Applicants' claimed method.

Furthermore, Applicants have discovered that, by the physical disruption treatment being carried out with adding an alkali, PHA can be advantageously obtained at high purity without decrease of molecular weight in fewer steps than Harrison's method, which uses three steps of alkaline treatment, then neutralization treatment, then physical disruption treatment. The unexpected results of Applicants' claimed physical disruption treatment being carried out with alkali treatment can not be predicted from Harrison's disclosure.

Therefore, for at least the above reasons, claim 1 and its dependent claims 2-7 are believed to be neither anticipated by nor obvious over Harrison. Withdrawal of the rejections is therefore requested.

103(a) Rejections

Claims 8 and 9 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Choi or Harrison in view of Huisman (USPA 2004-014197) or Yokomizo (US 7,083,972). Applicants traverse the rejections.

Choi in view of Huisman or Yokomizo

As stated above, Choi neither teaches nor suggests physical disruption treatment or physical disruption treatment being carried out with alkali treatment, as in Applicants' claimed method.

The deficiencies of Choi are not corrected by either Huisman or Yokomizo because neither reference discloses Applicants' claimed method.

Accordingly, claim 1 and dependent claims 8 and 9 are believed to be patentable over Choi in view of Huisman or Yokomizo. Withdrawal of the rejections is therefore requested.

Harrison in view of Huisman or Yokomizo

As stated above, Harrison neither teaches nor suggests physical disruption treatment being carried out with alkali treatment, as in Applicants' claimed method.

The deficiencies of Harrison are not corrected by either Huisman or Yokomizo because neither reference discloses Applicants' claimed method.

Accordingly, claim 1 and dependent claims 8 and 9 are believed to be patentable over Harrison in view of Huisman or Yokomizo. Withdrawal of the rejections is therefore requested.

Correction to Office Action

The Office Action, page 2, item 2, incorrectly lists the filing date of the corresponding PCT application PCT/JP03/05323 as "25 April 2002." However, the correct filing date is "25 April 2003." (Emphasis added.) Applicants request that the correction be made of record.

CONCLUSION

The claims are believed to be allowable. An early and favorable action to that effect is respectfully requested.

The Examiner is invited to contact the undersigned to discuss any issues regarding this application.

The Office is authorized to charge any fees or credit any overpayment to Kenyon & Kenyon deposit account no. 11-0600.

Respectfully submitted,

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